AMENDMENTS TO THE DRAWINGS

Attached is one sheet of replacement drawings containing Figure 11, to replace Figure 11 as originally filed.

Attachment: Replacement Sheet (1)

REMARKS/ARGUMENTS

Claims 1-27 are pending. By this Amendment, claims 1, 2 and 16 are amended, the specification is amended and claims 17-27 are added. Reconsideration in view of the above amendments and the following remarks are respectfully requested.

Claims 1, 2, 4-6, 10, 11 and 13 were rejected under 35 U.S.C. §102(b) over Choksi (U.S. Patent No. 4,360,018). This rejection is respectfully traversed.

Choksi is directed to an anesthesia system and method of filtering respiratory gas. Choksi includes disclosure of two embodiments, the first of which is shown in Figure 1 and includes a filter provided between a Y-shaped connection piece and an endotracheal tube 4. The second embodiment (Figure 5) includes a mask 42 rather than an endotracheal tube. In addition, the embodiment of Figure 1 differs from the embodiment of Figure 5 since the Figure 1 embodiment includes a canister to remove carbon dioxide, such that the anesthesia gas can be recycled via recycle conduit 13. Moreover, in the embodiment of Figure 1, no venting of the exhaled gas occurs since canister 12 removes CO_2. In the embodiment of Figure 5, the exhaled gas is discarded through a conduit 45. Choksi specifically states that while the non-recycled embodiment of Figure 5 is still in use (as of 1982), the preferred circuit is in Figure 1 which recycles the anesthesia gas. Without recycling, the anesthesia gas is simply lost, which is wasteful and potentially could affect personnel within the vicinity of the discarded gas.

Claim 1 is directed to a mask assembly comprising a patient interface in the form of a full face mask including a shell and a face contacting cushion, the patient interface defining a pressurized breathing chamber which in use communicates with a source of gas pressurized above atmospheric pressure, said pressurized breathing chamber being continuously pressurized in use at levels suitable for administration of continuous positive airway pressure (CPAP)

therapy to the patient, a gas washout vent positioned on or adjacent the patient interface to quietly exhaust exhaled gasses under pressure from the pressurized breathing chamber to atmosphere, and a filter assembly configured to receive gas exhaled by the patient in use, whereby the exhaled gas is vented to atmosphere in proximity to the patient interface following passage through said filter assembly.

Choksi does not teach or disclose this subject matter. Specifically, Choksi does not teach or suggest a patient interface in the form of a full face mask including a shell and a face contacting cushion. In Choksi, the embodiment of Figure 1 includes an endotracheal tube 1, whereas the embodiment of Figure 5 includes a mask 44 which does not appear to include both a shell and a face contacting cushion. Indeed, since such is not required in anesthesia applications since anesthesia is delivered on demand based on the patient's breathing activity.

In addition, Choksi does not teach or disclose that the patient interface defines a pressurized breathing chamber which in use communicates with a source of gas pressurized above atmospheric pressure, said breathing chamber being continuously pressurized in use at levels suitable for administration of continuous positive airway pressure (CPAP) therapy to the patient. Again, Choksi discloses an apparatus for use in anesthesia delivery which is conducted at atmospheric or near atmospheric pressures, whereby the anesthesia gas is delivered to the patient when the patient inhales. Thus, Choksi does not teach or suggest that the patient interface defines a pressurized breathing chamber which in use communicates with a source of gas pressurized above atmospheric pressure and which is suitable for treatment of CPAP therapy. As such, the structure in claim 1 is capable of treating the airways of a patient with increased air pressure to produce a pneumatic splinting effect in the airways and this is caused by the air pressure within the breathing cavity being suitable for treatment of CPAP therapy. Choksi is not

adapted to increase pressure to the claimed levels as per claim 1 and is not adapted for such treatment.

Further, Choksi does not teach or suggest a gas washout vent that is positioned on or adjacent the patient interface to quietly exhaust exhaled gases under pressure from the pressurized breathing chamber to atmosphere. In the embodiment of Figure 1, the gas is recycled such that it is not vented. Moreover, the pressure relief valve associated with the rebreathing bag 10 is not positioned on or adjacent the patient interface to quietly exhaust exhaled gases under pressure from the pressurized breathing chamber to atmosphere.

Finally, Choksi does not teach or suggest a filter assembly configured to receive gas exhaled by the patient in use, whereby the exhaled gas is vented to atmosphere in proximity to the patient interface following passage through said filter assembly. In Choksi, to the extent that gas is vented, it is not vented to atmosphere and proximity to the patient interface following passage through the filter assembly. It would also be undesirable to exhaust anesthesia gases in proximity to the patient.

In addition, Choksi does not teach or suggest the subject matter of the dependent claims. For example, Choksi does not teach that the filter has a viral efficiency of greater than 99.999%. In the Office Action, the Examiner alleges that Choksi specifies the claimed range, however, Choksi at column 3, lines 60-61 only discloses that the filter has an efficiency greater than 95%, and preferably about 99%.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 3, 7-9 and 12 were rejected under 35 U.S.C. §103(a) over Choksi. This rejection is respectfully traversed at least for the reason that claims 3, 7-9 and 12 depend from claim 1, either directly or indirectly. In addition, it is not obvious to modify Choksi to include a T-shaped

joint as specified in claim 3, since modification of the Y-shaped joint 5 in Choksi could result in different flow characteristics in the inhalation and exhalation tubes 6 and 7, amongst other issues.

In addition, in regard to claims 7 and 8, Applicants respectfully take issue with the Examiner's alleged admission in paragraph of the original specification. In particular, while Applicants note that calibration cap 56 is currently available from ResMed, there is no indication or hint that such calibration cap can be used in combination with the subject matter set forth in claim 5. Moreover, the Examiner is impermissibly relying on Applicants' own specification in order to establish a *prima facie* case for obviousness. Similar remarks apply to claim 9, in that although in-line vents were known prior to the present application, they were not known in combination with the subject matter of claim 1.

In regard to claim 12, Applicants appreciate the admission that Choksi does not disclose that the filter has an impedance of not greater than about 2 cm of water at about 60 liters per minute. However, the Examiner still rejects the claim since Choksi discloses that it is desirable that the filter has a low pressure drop of less than 0.3 inches of water at a gas flow rate of up to 12.5 liters of gas per minute. At the outset, Applicants respectfully submit that the ranges in Choksi are vastly different than the ranges set forth in claim 12. For example, while claim 12 sets forth an impedance of not greater than 2.0 cm of water at about 60 liters per minute, Choksi discloses a flow rate of up to 12.5 liters of gas, i.e., four to five times less than the claimed range. Moreover, the Examiner has shown no link between the impedance allowances in Choksi and that of claim 1, which is directed toward a mask assembly for use in continuous positive airway pressure (CPAP) therapy for patients who have sleep apnea or other respiratory disorders, requiring sufficient pressure in order to pneumatically splint open the patient's airways to be effective.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 14-16 were rejected under 35 U.S.C. §103(a) over Choksi in view of Gunaratnam (U.S. Patent No. 7,185,652).

At the outset, Applicants respectfully submit that Gunaratnam qualifies as prior art under 35 U.S.C. §102(e) and is commonly owned by the present Applicant, in which case it cannot be used in the context of a rejection under 35 U.S.C. §103(a). However, the Examiner's attention is directed to U.S. Patent No. 6,491,034 to Gunaratnam, which was patented on December 10, 2002.

In any event, Choksi and Gunaratnam are drawn to mutually exclusive structures one not lending itself to combination with the other. Specifically, Choksi is directed toward an anesthesia system in which gas is delivered to the patient at atmospheric or slightly above atmospheric levels, which pressure levels are not sufficient for use in gas delivery connection systems according to Gunaratnam, which is used in CPAP therapy.

Moreover, there is no apparent reason to provide Choksi with an anti-asphyxia valve since Choksi is used in the administration of anesthesia, which is closely monitored by a physician for patients who are undergoing some sort of surgery. As such, there is no motivation to provide Choksi with an anti-asphyxia valve, since the patient in an anesthesia application is being closely monitored and would not require or benefit from an anti-asphyxia valve.

Reconsideration and withdrawal of the rejection are respectfully requested.

The drawing was objected to since the anti-asphyxia valve was not shown in the drawings. A replacement Figure 11 is provided herewith in which an anti-asphyxia valve 80 has been schematically illustrated. In addition, paragraph [0039] of the specification has been amended to make reference to the now shown anti-asphyxia valve.

New claims 17-27 are presented for the Examiner's consideration.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4398-553.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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PTB:jck
Attachment: Replacement Figure 11

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